UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA
HARRISONBURG/ROANOKE DIVISIONS

ELLEN MASON, Plaintiff, v. PFIZER, INC., PHARMACIA LLC f/k/a PHARMACIA CORPORATION, PARKE, DAVIS & COMPANY LLC as successor-in-interest of PARKE, DAVIS & COMPANY, AND WARNER-LAMBERT COMPANY LLC f/k/a WARNER-LAMBERT COMPANY, Defendants.	No. 5:20–cv–00065

SARAH KATHRYN CROTTS, AN INCAPACITATED ADULT, WHO SUES BY AND THROUGH MARGIE STANLEY CROTTS, HER MOTHER, GUARDIAN AND NEXT FRIEND, Plaintiff, v. PFIZER, INC., PHARMACIA LLC f/k/a PHARMACIA CORPORATION, PARKE, DAVIS & COMPANY LLC as successor-in-interest of PARKE, DAVIS & COMPANY, AND WARNER-LAMBERT COMPANY LLC f/k/a WARNER-LAMBERT COMPANY, Defendants.	No. 7:20-cv-00601-TTC

DEFENDANTS' SUPPLEMENTAL BRIEF REGARDING
JUDICIAL NOTICE AND PREEMPTION

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Defendants respectfully submit this supplemental brief at the Court's direction (*see Mason* Doc. 45; *Crotts* Doc. 48) to address (1) whether the Court may take judicial notice of the time periods during which these two Plaintiffs ingested Dilantin, and (2) whether the Court may decide impossibility preemption on a motion to dismiss (and, particularly, whether the Court may dismiss these claims as a matter of law where Plaintiffs have failed to identify any "newly acquired information" that would have allowed Defendants to unilaterally change the Dilantin FDA-approved warning label under FDA regulations).[1]

I. The Court can take judicial notice of Plaintiffs' dates of Dilantin/phenytoin use from the parties' briefing and Plaintiffs' New York Plaintiff Fact Sheets, submitted here.

The Court can take judicial notice of the uncontested fact that Plaintiffs Ellen Mason and Sarah Crotts took Dilantin *after* the 2015 addition of the words "cerebellar atrophy" to the Dilantin label, despite Plaintiffs' admittedly vague pleadings.[2] Plaintiff Mason alleged only that she "took branded Dilantin for several years" (*see Mason* Doc. 1 ¶ 14), and Plaintiff Crotts alleged only that she "was prescribed and ingested Dilantin for more than a decade" (*see Crotts* Doc. 1 ¶ 14). But Plaintiffs previously filed suit as part of multi-plaintiff complaints in New York state court.[3] *See Mason* Doc. 15, at 4–5; *Crotts* Doc. 18, at 4–5. Their cases were coordinated with those of other plaintiffs represented by this same Plaintiffs' counsel here, as *In re Dilantin Litigation*, Index No.

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[1] For sake of efficiency, Defendants are filing this supplemental brief in both the *Mason* case (No. 5:20–cv–00065) and the *Crotts* case (No. 7:20–cv–00601). Defendants filed substantively identical motions to dismiss in both cases because both Plaintiffs were prescribed and used Dilantin/phenytoin after December 2015 (*Mason* Doc. 15; *Crotts* Doc. 18), and the Court heard combined oral argument in the two cases on January 13, 2021.

[2] *See, e.g.*, *Mason* Doc. 35, at 12 (noting that "Plaintiff does not allege in the complaint that she took Dilantin after the label change," but not disputing that fact); *Crotts* Doc. 38, at 12 (same).

[3] Plaintiff Mason was part of a complaint captioned *DeLumeau v. Pfizer*, No. 26098/2019E (N.Y. Sup. Ct. May 23, 2019) (*see Mason* Doc. 15, at 4), and Plaintiff Crotts was part of *Monacelli v. Pfizer*, No. EFCV-19-156675 (N.Y. Sup. Ct. Oct. 2, 2019) (*see Crotts* Doc. 18, at 4).

784000/2019 (N.Y. Sup. Ct.). In those state coordinated proceedings, both Plaintiffs submitted a completed court-approved Plaintiff Fact Sheet ("PFS"), signed under penalty of perjury.

In her PFS, Plaintiff Mason attests that she was prescribed and used Dilantin from 1995–2017. *See Mason* Doc. 15, at 8. And Plaintiff Crotts's PFS, signed by her personal representative, attests that Crotts was prescribed and used Dilantin from 2004–2018. *See Crotts* Doc. 18, at 8. Defendants asserted these dates of use in their motions to dismiss—indeed, the fact that Plaintiffs were prescribed and used Dilantin/phenytoin after the 2015 label change was the basis of Defendants' arguments for dismissal. *See Mason* Doc. 15, at 8–9; *Crotts* Doc. 18, at 8–9. Notably, Plaintiffs' opposition did not dispute those dates—Plaintiffs asserted only that they "do[] not allege in the[ir] complaint[s] that [they] took Dilantin after the label change," so "there is nothing in the complaint[s] that supports Defendants' causation argument[s] at the pleadings stage." *Mason* Doc. 35, at 12; *Crotts* Doc. 38, at 12. The remainder of Plaintiffs' arguments "[a]ssum[ed] that Plaintiff[s] took Dilantin after the 2015 label change." *Mason* Doc. 35, at 12; *Crotts* Doc. 38, at 12. Likewise, Plaintiffs' counsel did not dispute at the January 13, 2021 hearing that Plaintiffs were prescribed and continued to use the medicine after December 2015, and counsel did not have an answer for why these dates were omitted from Plaintiffs' complaints.

This Court can take judicial notice of these undisputed dates of use because they come from Plaintiffs' *own sworn statements*—thus, they cannot be reasonably disputed, nor have they been. *See* Fed. R. Evid. 201(b); *see also, e.g.*, *Korman v. Iglesias*, No. 18-21028-CV, 2018 WL 4410226, at *2 (S.D. Fla. June 28, 2018) (taking judicial notice of plaintiff's affidavit and deposition testimony from prior case because they contained "fact[s] that [were] undoubtedly central" to the plaintiff's claims and the plaintiff "ha[d] not disputed the[ir] authenticity"); *Sutphin v. Zontrom, LLC*, No. 6:09-cv-1614, 2009 WL 10712868, at *3 (M.D. Fla. Dec. 18, 2009) (taking

judicial notice of the "*same Plaintiff*[*'s*]" sworn testimony "in an earlier case"). To avoid doubt—as the Court suggested, Defendants are contemporaneously submitting to the Court (under seal to protect Plaintiffs' confidential personal information) the sworn PFSs of Plaintiffs Mason and Crotts. Again, Plaintiff Mason's PFS, signed under penalty of perjury, attests that she was prescribed Dilantin from 1995–2017. *See* Mason PFS at 18, 25. Plaintiff Crotts's PFS, which her representative signed under penalty of perjury, attests that Crotts was prescribed Dilantin from 2004–2018. *See* Crotts PFS at 16, 26.

This Court can take judicial notice of the facts in Plaintiffs' PFSs without converting this motion into one for summary judgment. *See, e.g.*, *Wiendieck v. Wells Fargo Bank, N.A.*, No. 3:16-cv-00034, 2016 WL 4444916, at *5 (W.D. Va. Aug. 23, 2016) (explaining that a court may consider "'matters of which a court may take judicial notice' without converting the motion into one for summary judgment" (quoting *Tellabs., Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007))). And it should—"[t]he purpose of allowing judicial notice of such facts and documents 'is to prevent parties from surviving a motion to dismiss by artful pleading or by failing to attach relevant documents.'" *Rao v. Gondi*, No. 14 C 66, 2014 WL 5423441, at *3 n.1 (N.D. Ill. Oct. 23, 2014) (quoting *188 LLC v. Trinity Indus., Inc.*, 300 F.3d 730, 735 (7th Cir. 2002)).

Leggat v. Equifax Information Services, Inc., No. 3:09–CV–263, 2009 WL 2432371, at *2 (E.D. Va. Aug. 6, 2016), makes the point. There, the court noted that district courts "may consider official public records, documents central to a plaintiff's claim, and documents sufficiently referred to in the Complaint without converting the motion to dismiss into one for summary judgment, so long as the authenticity of such document is not disputed." Thus, the court held that it could "consider uncontested documents which are relevant to the disposition of a motion to dismiss." *Id.* In that case, "[t]he Complaint—whether intentionally or inadvertently—omit[ted]

the dates of [the] repossession and sale of the vehicle at issue," even though the "dates [we]re central to Plaintiff's claim." *Id.* at *1–2. The defendant in that case submitted an affidavit asserting those dates as part of its motion to dismiss, and the "[p]laintiff acknowledge[d] the information in the affidavit [wa]s correct." *Id.* at *2. Because "the facts contained within the affidavit [we]re central to Plaintiff's claim and [we]re uncontested, the Court . . . consider[ed] them without conversion to summary judgment." *Id.* The court then granted the defendant's motion to dismiss on statute-of-limitations grounds. *Id.*

All the more, here: The submitted PFSs are not affidavits from a *defendant*, but rather *Plaintiffs' own sworn statements*, which state their uncontested dates of Dilantin/phenytoin use. This Court therefore can—and should—take judicial notice of those dates and dismiss Plaintiffs' claims with prejudice because Plaintiffs cannot prove causation, as a matter of law.

II. Federal law preempts Plaintiffs' claims that the Dilantin label remained inadequate after December 2015, and the Court can decide that issue on the pleadings.

Under the impossibility preemption doctrine, "a state-law challenge to federally approved pharmaceutical warning labels may only proceed when the pharmaceutical company has the unilateral ability to change that labeling." *Knight v. Boehringer Ingelheim Pharms., Inc.*, __ F.3d __, 2021 WL 41897, at *1 (4th Cir. Jan. 6, 2021). The FDA's "changes-being-effected ('CBE') regulation permits pharmaceutical companies to unilaterally modify their physician labels only to 'add or strengthen a . . . warning' based upon 'newly acquired information' about 'evidence of a causal association' between the drug and a risk of harm." *Id.* (quoting 21 C.F.R. § 314.70(c)(6)(iii)). Here, then, to proceed on their claims that the Dilantin label remained inadequate after the December 2015 label change, Plaintiffs must plausibly allege that Defendants thereafter obtained "newly acquired information"—a term with a specific regulatory definition, *see* 21 C.F.R. § 314.3(b)—that would have allowed Defendants to unilaterally change the label.

Plaintiffs have not done so, and this Court can readily consider that issue on a motion to dismiss. Indeed, two federal courts of appeals have affirmed the dismissal of state-law tort claims on the pleadings where, like here, the plaintiffs failed to identify "newly acquired information." *See Gibbons v. Pfizer Inc.*, 919 F.3d 699, 709 (2d Cir. 2019); *In re Celexa & Lexapro Mktg. & Sales Pracs. Litig.*, 779 F.3d 34, 42–43 (1st Cir. 2015). So have numerous district courts, including where the plaintiffs alleged (like here) that the FDA-approved warnings *remained* inadequate after a label change. *See infra* at 8–9 & n.4. This Court can—and should—dismiss Plaintiffs' claims here for the same reason.

A. Impossibility preemption can be decided on a motion to dismiss.

Federal preemption is an issue of law and, accordingly, can be decided on a motion to dismiss. If a plaintiff fails to plausibly allege that the pharmaceutical-company defendant had certain "newly acquired information" that would allow it to use the CBE regulation to unilaterally change its product's label, the plaintiff's claims should be dismissed on the pleadings.

1. Federal preemption is a question of law.

Consistent with the Supremacy Clause, "'it has long been settled that state laws that conflict with federal law are without effect.'" *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1678 (2019) (quoting *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 479–80 (2013)). "[S]tate and federal law conflict"—and state law is thus preempted—"where it is 'impossible for a private party to comply with both state and federal requirements.'" *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 618 (2011) (internal quotation marks omitted).

Most recently, in *Albrecht*, the Supreme Court explained that whether federal law preempts a plaintiff's state-law tort claim in this context is a legal question. 139 S. Ct. at 1676 ("We here decide that a judge, not the jury, must decide the pre-emption question."). Following *Albrecht*, the Fourth Circuit too has held that federal "[p]reemption is a question of law." *Knight*, 2021 WL

41897, at *5 & n.8 (citing *Albrecht*, 139 S. Ct. at 1676). And because preemption is an issue of law, it may be decided on a motion to dismiss: "Rule 12(b)(6) authorizes a court to dismiss a claim on the basis of a dispositive issue of law." *Sons of Confederate Veterans, Va. Div. v. City of Lexington*, 722 F.3d 224, 228 (4th Cir. 2013) (internal quotation marks omitted).

Impossibility preemption in pharmaceutical cases is no exception to that general rule. *See, e.g.*, *Drager v. PLIVA USA, Inc.*, 741 F.3d 470, 479 (4th Cir. 2014) (affirming judgment on the pleadings based on preemption). A review of the Supreme Court's impossibility-preemption precedents and the regulatory framework applicable to prescription medications shows why.

Four recent Supreme Court decisions have outlined the test for "impossibility" preemption in pharmaceutical cases: *Wyeth v. Levine*, 555 U.S. 555 (2009); *Mensing*, 564 U.S. 604 (2011); *Bartlett*, 570 U.S. 472 (2013); and *Albrecht*, 139 S. Ct. 1668 (2019). Together, these decisions explain that "[t]he question for 'impossibility' is whether the [defendant manufacturer] could independently do under federal law what state law requires of it." *Mensing*, 564 U.S. at 620; *see also Bartlett*, 570 U.S. at 475 (citing *Mensing*).

The answer to that question flows from FDA's comprehensive regulation of prescription medicines. Relevant here, once FDA approves a medication, a manufacturer generally "may only change a drug label after the FDA approves a supplemental application." *Levine*, 555 U.S. at 568. In limited circumstances, "drug manufacturers [may] change a label without prior FDA approval," using the CBE regulation, *id.*, which allows the manufacturer to add or strengthen warnings without advance FDA approval *only if*, among other things, the change is made "to reflect newly acquired information," 21 C.F.R. § 314.70(c)(6)(iii). *See also Knight*, 2021 WL 41897, at *6; *Albrecht*, 139 S. Ct. at 1673 (recognizing requirement of "newly acquired information" to invoke the CBE procedure).

So the first question is whether the manufacturer had "'newly acquired information' as defined in the CBE regulation that could have justified a unilateral change in the [product's] label." *Knight*, 2021 WL 41897, at *6. "To answer that question," courts must start "with the definition of 'newly acquired information,'" *id.*: "data, analyses, or other information not previously submitted to the agency, which may include (but are not limited to) data derived from new clinical studies, reports of adverse events, or new analyses of previously submitted data (e.g., meta-analyses) if the studies, events or analyses reveal risks of a different type or greater severity or frequency than previously included in submissions to FDA." 21 C.F.R. § 314.3(b). If the manufacturer lacked "newly acquired information," then it could not have acted unilaterally to change the label. But because FDA retains authority to reject label changes, even if a manufacturer can act unilaterally, a state-law claim is still preempted if there is "clear evidence" that FDA would not have approved a change to the label. *See, e.g.*, *Albrecht*, 139 S. Ct. at 1672.

2. Federal courts routinely consider impossibility preemption of claims against pharmaceutical manufacturers on motions to dismiss.

Federal courts have distilled the regulatory framework and the Supreme Court's decisions into a two-part test that is readily applied at the motion-to-dismiss stage.

To allege a non-preempted claim, a plaintiff first "must plead 'a labeling deficiency that [Defendants] could have corrected using the CBE regulation.'" *Gibbons*, 919 F.3d at 708 (quoting *Celexa*, 779 F.3d at 41). To do so, the plaintiff must "provide plausible allegations of 'newly acquired information'" arising after FDA's approval of the relevant label. *See, e.g.*, *Goodell v. Bayer Healthcare Pharms., Inc.*, No. 18-cv-10694-IT, 2019 WL 4771136, at *4 (D. Mass. Sept. 30, 2019); *see also* Part II.B.1 *infra*. Only "[i]f the plaintiff meets that standard" does the burden then "shift[] to the party asserting a preemption defense to demonstrate that there is clear evidence

that the FDA would not have approved a change to the [prescription drug's] label." *Gibbons*, 919 F.3d at 708 (last alteration in original) (citation and internal quotation marks omitted).

Indeed, because preemption is a question of law, "when a complaint does not plausibly allege any non-preempted claim, it must be dismissed under Rule 12(b)(6)," *Maze v. Bayer Healthcare Pharms., Inc.*, No. 4:18-CV-21-TAV-CHS, 2019 WL 1062387, at *2 (E.D. Tenn. Mar. 6, 2019), and federal courts routinely dismiss claims at the Rule 12 stage—including in pharmaceutical cases—because federal law preempts them, *see, e.g.*, *Drager*, 741 F.3d at 479.

a. Federal courts have dismissed state-law claims on the pleadings where plaintiffs fail to plausibly allege "newly acquired information."

If Plaintiffs fail to plausibly allege the existence of "newly acquired information" post-dating FDA's approval of the label, their claims fail at step one and may be dismissed on the pleadings. In such a case, discovery is unnecessary and improper. *See, e.g.*, *Utts v. Bristol-Myers Squibb Co.*, 251 F. Supp. 3d 644, 672–73 (S.D.N.Y. 2017). In *Utts*, for example—a case involving the prescription medicine Eliquis—the plaintiffs, like here, argued that preemption is "'necessarily fact-specific'" and should thus "be decided no earlier than at summary judgment." *Id.* at 672. The district court disagreed, explaining that "[i]t is well-established that preemption may be analyzed and decided at the motion to dismiss stage" because "a determination regarding preemption is a conclusion of law." *Id.* (internal quotation marks omitted). And although the plaintiffs requested "an opportunity to pursue discovery," the court pointed out that "they [were] not entitled to discovery on preempted claims." *Id.*

The Second Circuit later affirmed the *Utts* court's rationale. *Gibbons*, 919 F.3d at 709. In *Gibbons*, the Second Circuit held that the district court "properly dismissed" the plaintiffs' failure to warn claims as preempted by federal law. *Id.* As the court explained, the operative complaint "consist[ed] of 'conclusory and vague' allegations and d[id] not plausibly allege the existence of

newly acquired information that could have justified Defendants' revising the [product's] label through the CBE regulation." *Id.* And the First Circuit has also affirmed the preemption-based dismissal of claims against pharmaceutical manufacturers on the pleadings. *See In re Celexa*, 779 F.3d at 42–43 (affirming Rule 12 dismissal of plaintiffs' complaint for failure to allege "newly acquired information" that would have allowed the manufacturer to change the label).

These decisions accord with the Fourth Circuit's decision in *Knight*, which held *as a matter of law* (although after a jury trial) that the plaintiffs' claims were preempted because the manufacturer "did not have 'newly acquired information' . . . which would have warranted a unilateral change to the physician label." 2021 WL 41897, at *5–8.

Nor are these decisions outliers—federal courts routinely dismiss state-law claims on the pleadings if the plaintiff does not plausibly allege the existence of specific "newly acquired information" that would allow the defendant to unilaterally change the label.[4]

b. The "clear evidence" inquiry only ripens once Plaintiffs identify newly acquired information.

Although Plaintiffs' counsel alluded to the "clear evidence" standard at the hearing on Defendants' motion to dismiss, the Court need not reach that issue. A defendant's burden to show

[4] *Accord, e.g.*, *Gayle v. Pfizer Inc.*, 452 F. Supp. 3d 78, 87–89 (S.D.N.Y. 2020); *Javens v. GE Healthcare Inc.*, No. 18-1030-RGA-SRF, 2020 WL 2783581, at *3 (D. Del. May 29, 2020), *report and recommendation adopted*, 2020 WL 7051642 (D. Del. June 18, 2020); *Burgess v. Pfizer Inc.*, No. 7:19-CV-235-FL, 2020 WL 1812010, at *4 & n.2 (E.D.N.C. Apr. 9, 2020); *Smith v. GE Healthcare Inc.*, No. 3:19-CV-00492, 2020 WL 1880787, at *6 (W.D. La. Mar. 31, 2020); *Mahnke v. Bayer Corp.*, No. 2:19-cv-07271-RGK-MAA, 2020 WL 2048622, at *2–5 (C.D. Cal. Mar. 10, 2020); *Goodell*, 2019 WL 4771136, at *4; *McGrath v. Bayer HealthCare Pharms. Inc.*, 393 F. Supp. 3d 161, 168–71 (E.D.N.Y. 2019); *Maze*, 2019 WL 1062387, at *3–4; *McGee v. Boehringer Ingelheim Pharms., Inc.*, No. 4:16-CV-2082-KOB, 2018 WL 1399237, at *3–5 (N.D. Ala. Mar. 20, 2018); *Ideus v. Teva Pharms. USA, Inc.*, No. 4:16-CV-3086, 2017 WL 6389630, at *2–3 (D. Neb. Dec. 12, 2017); *Utts*, 251 F. Supp. 3d at 662–72 (all granting Rule 12 motions to dismiss or for judgment on the pleadings in pharmaceutical cases, based on failure to plausibly allege the existence of "newly acquired information").

that there is "clear evidence that the FDA would not have approved a change to the [prescription drug's] label," *Gibbons*, 919 F.3d at 708, arises *only if* the plaintiff *first* alleges a claim that is not preempted—*i.e.*, plausibly alleges the existence of newly acquired information. *See Gayle*, 452 F. Supp. 3d at 88 (holding that defendant was not required to meet the "clear evidence" inquiry until plaintiff "demonstrate[d] the existence of 'newly acquired information'"). So "[i]f this preliminary showing is not made, the court need not reach a determination of whether the defendant has shown clear evidence that the FDA would have rejected the proposed label change." *Javens*, 2020 WL 2783581, at *5; *see also, e.g.*, *McGrath*, 393 F. Supp. 3d at 171 ("[B]ecause Bayer could not have amended the warning under the CBE regulation, this Court need not even consider whether there is clear evidence the FDA would not have approved a change to [the medicine's] label.").

The "clear-evidence" question is thus a secondary one, and the Court need not reach that issue if the plaintiffs do not allege that there is newly acquired information to support a unilateral label change in the first place.

B. Plaintiffs have failed to allege a non-preempted claim that the Dilantin label was inadequate post-2015, and the Court should thus dismiss their claims.

Here, the Court should dismiss Plaintiffs' claims on the pleadings because Plaintiffs have not plausibly alleged a non-preempted claim that the Dilantin label remained inadequate after FDA approved the updated label in December 2015.

1. Plaintiffs have not alleged any "newly acquired information" that arose after FDA approved the Dilantin label with a specific reference to "cerebellar atrophy" in December 2015.

To avoid preemption, numerous courts have held that a plaintiff must plausibly allege the existence of specific "newly acquired information" that *post-dates* the product's label change. *See, e.g.*, *Mahnke*, 2020 WL 2048622, at *3 ("This newly acquired information must have been available to Bayer after the FDA approved the relevant label on August 19, 2010 . . . ."); *Goodell*,

2019 WL 4771136, at *4 ("[T]he complaint does not cite any newly acquired information that arose after the FDA's approval of Magnevist's revised label in 2007 . . . ."); *Maze*, 2019 WL 1062387, at *3 (explaining that the complaint failed to allege the existence of "newly acquired information" after the FDA approved the label change and before the plaintiff's injury). The reason that "newly acquired information" must post-date FDA's approval of the relevant label is that preemption turns on whether the *manufacturer* can unilaterally (*i.e.*, *itself*) change the approved label: A "state-law challenge to federally approved pharmaceutical warning labels may only proceed" if the defendant "has the unilateral ability to *change* that labeling." *Knight*, 2021 WL 41897, at *1 (emphasis added). New information that would allow the manufacturer to further change the label necessarily must arise after FDA approved it. *See Albrecht*, 139 S. Ct. at 1673 ("FDA regulations also acknowledge that information about drug safety may change over time, and that *new information* may require *changes* to the drug label." (emphasis added)).

Plaintiffs have alleged no regulatorily-defined "newly acquired information" that "would have warranted a [further] unilateral change to the physician label," *Knight*, 2021 WL 41879, at *8—*i.e.*, information arising after December 2015 revealing new, more severe, or more frequent risks about cerebellar atrophy. As a result, their claims are preempted. Indeed, federal courts have rejected failure-to-warn claims in this very context, involving proposed updates to an FDA-approved label. *See, e.g.*, *Gayle*, 452 F. Supp. 3d at 87–89; *Maze*, 2019 WL 1062387, at *1. In *Maze*, for example, the plaintiffs alleged that the defendant failed to adequately warn of the risk of stroke associated with the prescription birth-control medication Yaz. 2019 WL 1062387, at *1. But FDA had approved an updated label in 2012 that warned of the stroke risk. *Id.* The court held that the plaintiffs' claims were preempted because the complaint could "not plausibly be read to contain any 'newly acquired information,' or even a 'new analys[i]s of previously submitted data,'

on the basis of which [the defendant] could have changed the Yaz label using the CBE process, at sometime between 2012 and [the injury] in 2015." *Id.* at *3 (granting motion to dismiss).

Likewise, in *Gayle*, the district court granted a motion for judgment on the pleadings based on the plaintiff's failure to allege newly acquired information obtained after FDA approved the product's label change. 452 F. Supp. 3d at 87–89. The court held that any claims that "arose after the 2012 Lipitor label change" were preempted because the plaintiffs had not pointed to any "newly acquired information that could have justified Defendants' revising the [Lipitor] label through the CBE regulation." *Id.* (quoting *Gibbons*, 919 F.3d at 708).

The upshot is this: Plaintiffs' failure to allege any information arising *after* FDA's December 2015 approval of the Dilantin label that "reveal[s] risks of a different type or greater severity or frequency than previously included in submissions to FDA" about cerebellar atrophy means that their claims are preempted.

2. Plaintiffs cannot point to information that arose before December 2015 to avoid preemption.

Lacking any plausible allegations that Defendants had "newly acquired information" after December 2015, Plaintiffs try instead to turn back the clock. At oral argument, Plaintiffs' counsel suggested that FDA may not have seen certain documents before it approved the revised Dilantin label in December 2015. That argument cannot save Plaintiffs' claims, for multiple reasons.

1. Such a claim impermissibly second-guesses FDA's decision to approve the updated Dilantin label and its specific reference to cerebellar atrophy in December 2015. As described above, during the approval process for a new medicine, manufacturers "work with the FDA to develop an appropriate label." *Albrecht*, 139 S. Ct. at 1673. In fact, "[t]he application must include the proposed label's text 'with annotations to the information in the [drug application] that support the inclusion of each statement [on the label]." *In re Celexa*, 779 F.3d at 36 (quoting 21 C.F.R.

§ 314.50(c)(2)(i)). And FDA's approval of a medication "includes the approval of the exact text in the proposed label." *Levine*, 555 U.S. at 568. Because the federal regulatory scheme makes FDA the "exclusive judge of [a medicine's] safety and efficacy based on information available at the commencement of marketing," *In re Celexa*, 779 F.3d at 41, federal law preempts failure-to-warn claims "premised on the adequacy of the label as approved by the FDA when the drug was first marketed," *Utts v. Bristol-Myers Squibb Co.*, 226 F. Supp. 3d 166, 184–85 (S.D.N.Y. 2016).[5]

That same logic applies to a claim that an *updated label* was inadequate, at least where the label was updated to address the very condition that forms the basis of the plaintiff's claims. That is so because under federal law, "[a]ll procedures and actions that apply to a[new drug] application under § 314.50 also apply to supplements." 21 C.F.R. § 314.71. So to secure the approval of the updated Dilantin label in December 2015, Defendants had to provide FDA "the proposed label's text 'with annotations to the information in the [drug application] that support the inclusion of each statement [on the label].'" *In re Celexa*, 779 F.3d at 36 (quoting 21 C.F.R. § 314.50(c)(2)(i)). And FDA considered that information in approving the December 2015 label's reference to cerebellar atrophy. *See id.* ("[T]o approve an NDA or sNDA, the FDA must determine, 'based on a fair evaluation of all material facts,' that the proposed label is not 'false or misleading in any particular [way].'").

Federal law prohibits judicial second-guessing of FDA's decision to approve a specific warning in an updated label. As one court put it, "whether a nonexistent warning should be included on a label at all" is a different question than "the adequacy of the FDA-approved" warning

[5] *See also, e.g.*, *Bell v. Boehringer Ingelheim Pharms., Inc.*, No. 17-1153, 2018 WL 2447788, at *6 (W.D. Pa. May 31, 2018) ("Failure to warn claims based upon alleged deficiencies in the initial label are preempted."); *McGee*, 2018 WL 1399237, at *4 (similar); *Utts*, 251 F. Supp. 3d at 660 (holding that "federal law preempts all pre-FDA approval failure to warn and design defect claims for branded prescription medication").

included in a revised label. *Maze*, 2019 WL 1062387, at *3. "The former is heads-or-tails, the latter involves matter-of-degree questioning with respect to something that was clearly known and considered by the FDA [when it approved the updated label]." *Id.* And without a showing that there is newly acquired information post-dating FDA's consideration and approval of a cerebellar atrophy reference, such a claim "second guess[es]" FDA's approval of the label. *Id.*

2. Any suggestion that Defendants withheld information from FDA in seeking agency approval runs into a different preemption problem—*Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). In *Buckman*, the Supreme Court held that federal law preempts a claim that a manufacturer "made fraudulent representations to the FDA" to obtain "market clearance." 531 U.S. at 347–49. The Court explained that allowing state law to police fraud on FDA would "conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives." *Id.* at 350. Here, as just explained, Defendants had a regulatory obligation to "include the proposed label's text 'with annotations to the information in the [drug application] that support the inclusion of each statement" regarding cerebellar atrophy on the label. *Buckman* thus bars a claim that Defendants concealed some information about cerebellar atrophy from FDA while submitting other information to FDA to obtain approval of the original or supplemental NDAs. *See, e.g.*, *id.*; *Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319, 1330 (11th Cir. 2017) (federal law preempts failure-to-report claim); *Burrell v. Bayer Corp.*, 260 F. Supp. 3d 485, 492 (W.D.N.C. 2017) (same).

3. Even so, information is not "newly acquired information" under federal law just because FDA has not seen it. Instead, as explained above, the "newly acquired information" requirement is part of the test for when a pharmaceutical company can unilaterally change its label. So the question necessarily is whether *the company* (not FDA) *acquires* some *new* information.

Moreover, by definition, "newly acquired information" exists where the information (1) was not previously submitted to the Agency ***and*** (2) "reveal[s] risks of a different type or greater severity or frequency than previously included in submissions to FDA." 21 C.F.R. § 314.3(b). *Knight* itself makes the point—there, the Fourth Circuit rejected internal emails and a "draft paper's preliminary assessments" as newly acquired information because they did not "reflect[] a revelation of risks of a different type or greater severity or frequency" relating to the risk at issue. 2021 WL 41897, at *7. Plaintiffs cannot escape preemption just by arguing that FDA did not see some document(s) that predated the December 2015 label change.

But even if information about cerebellar atrophy predating the December 2015 label change could qualify as "newly acquired information" (and it cannot, both because of the federal regulatory scheme and *Buckman* preemption), Plaintiffs' claims still would fail. "Newly acquired information" must reveal different, more severe, or more frequent risks than was revealed in other information submitted to FDA. 21 C.F.R. § 314.3(b). Plaintiffs have not plausibly alleged that Defendants possessed *any* information that meets that regulatory requirement. *See, e.g.*, *Gibbons*, 919 F.3d at 708 (affirming dismissal of complaint that "provide[d] no basis upon which the court could conclude that the bleeding events covered by the alleged reports and studies presented a different type of risk than those the company had discussed with the FDA, or were more severe or more frequent than bleeding events that the government already knew about").

CONCLUSION

For the foregoing reasons, this Court can and should take judicial notice of the time periods during which Plaintiffs were prescribed and used Dilantin. The Court also can decide on the pleadings whether federal law preempts Plaintiffs' claims that the amended December 2015 Dilantin label, which added "cerebellar atrophy," remains inadequate.

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CERTIFICATE OF SERVICE

I hereby certify that, on January 22, 2021, I caused the foregoing document to be electronically filed through the Court's CM/ECF system, which caused a notice of electronic filing and copy of the foregoing to be served on all counsel of record.

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